K000672
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510(K) Summary
for
Heliodent Vario

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstraße 31
D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 3294

Date Prepared: February 21, 2000

2. DEVICE NAME

Proprietary Name:	Heliodent Vario
Common/Usual Name:	Intraoral X-ray system
Classification Name:	Extraoral source X-ray system

3. PREDICATE DEVICES

Heliodent 60 (preamendment)
Gendex GX-770 (K935046)
Dent-X image-x 70 (K930761)

4. INTENDED USE

The Heliodent Vario is intended to be used for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

5. DEVICE DESCRIPTION

The Heliodent Vario is an extraoral source dental X-ray system intended for intraoral imaging. X-rays are produced using an AC single pulse generator with a tube

voltage of 70 kV and a tube current of 7 mA. A microprocessor-controlled timer allows for consistent and accurate exposure control, and an adjustable arm allows for easy positioning. The system can be used either with conventional film or a digital imaging system, such as the SIDEXIS Digital Radiography System (see K972168). The system software automatically adjust for the shorter exposure times required when operating in digital imaging mode.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The claim of substantial equivalence for the Heliodent Vario is based on both intended use and technical specifications. The Heliodent Vario has the same intended use as the predicate devices, that is, for radiographic imaging and diagnosis of diseases of the teeth, jaw, and oral structures. Technical specifications of the Heliodent Vario are the same or very similar to those of the predicate devices. All devices generate the X-ray radiation using a AC source. The characteristics of the X-ray tube, including tube voltage, tube current, focal spot, focal length and X-ray filtration, and the X-ray exposure times are all within equivalent ranges. The newer systems, including the Heliodent Vario, the Gendex, and the Dent-X systems, are all compatible with both conventional film and digital imaging radiography.

The following table presents a comparison of the specifications for the Heliodent Vario and the predicate devices.

Specification	Heliodent Vario	Heliodent 60	Gendex gx-770	Dent-X Image-X 70
Line requirements	100V/110V/120V, 11A 220V/230V/240V, 6A 50Hz/60Hz	125V, 10 A 220V, 6 A 50Hz/60Hz	110V-130 60Hz	110V/220V 50Hz/60Hz
Generator type	AC single pulse	AC single pulse	AC	AC
Tube voltage	70 kV	52 kV	70 kV	70 kV
Tube current	7 mA	7 mA	7 mA	8 mA
Exposure time selection	0.03 – 3.2 sec	0.7-36 mAs at nominal voltage	3-99 impulses (28 steps)	0.08-3.2 sec
Focal spot	0.8 mm	0.8 mm x 0.8 mm	0.6 mm	0.7 mm x 0.7 mm
Focal length	8 in./12 in.	8 in./12 in.	8 in./12 in.	8 in./12 in.
Total filtration in X-ray tube unit	> 2 mm Al	> 2 mm Al	Unknown	> 2.5 mm Al
Leakage radiation	0.25 mGy/h (at 0.25 mA/70 kV)	unknown	unknown	< 28 mR/hr at 1 m from focal spot
Compatible with film and digital imaging	Yes	No	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Sirona Dental Systems GMBH
C/O Sheila Hemeon-Heyer, J.D., RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K000672
Sirona Dental Systems Heliodent Vario
Dated: February 25, 2000
Received: February 28, 2000
Regulatory class: II
21 CFR 872.1800/Procode: 90 EHD

Dear Ms. Sheila Hemeon-Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K000672

Device Name: HELIODENT VARIO

Indications For Use:

The Heliodent Vario is an Extraoral Source X-ray System, intended to be used for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

(Please do not write below this line –Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000672